Practitioner's Docket No. 700953-047113-C2 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jeffrey Schlom; Judith Kantor; Donald Kufe; Dennis Panicali, and Linda Gritz
Application No.: To be assigned (Con't of 09/366,670) Group No.: To be assigned
Filed: To be assigned (August 3, 1999) Examiner: To be assigned
For: RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST MUC1 TUMOR-ASSOCIATED ANTIGEN

CERTIFICATE OF MAILING

I hereby certify that this correspondence, on the date shown below, is being deposited with the United States Postal Service with sufficient postage as Express Mail Label No. EL565093478US in an envelope addressed to Assistant Commissioner of Patents, Washington, D.C. 20231.

Date: January 25, 2002

Nicole M. Gignac

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT

This Preliminary Amendment is being filed in the U.S. Patent and Trademark Office concurrently with the U.S. National Phase Entry of the above-identified application.

Preliminary to calculation of the filing fee and examination on the merits, please amend the application identified in caption as follows.

IN THE SPECIFICATION:

Please insert the following heading and paragraph as the first paragraph on the first page in the application:

CROSS-REFERENCE TO RELATED APPLICATIONS

The following application is a continuation of U.S. Serial No. 09/366,670 filed on August 3, 1999, which is a continuation of PCT/US98/03693 filed on February 24, 1998, now abandoned, which claimed benefit under 35 U.S.C. §119 of U.S. Provisional Application 60/038,254 filed on February 24, 1997.

IN THE CLAIMS:

Please cancel claims 1 - 22.

Please add the following new claims:

23. A recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising approximately 5 to *25* MUC1 tandem repeat units, wherein said nucleic acid sequence is altered from the native tandem repeat pattern by using alternative codons to reduce homology between the repeats.

24. The recombinant pox virus of claim 1, wherein the immunogenic MUC1 fragment comprises approximately 7 to 15 MUC1 tandem repeat units.

25. The recombinant pox virus of claim 2, wherein the immunogenic MUC1 fragment comprises 10 MUC1 tandem repeat units.

26. The recombinant pox virus of claim 1, wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.

27. A pharmaceutical composition comprising:
(a) a recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising approximately 5 to 25 MUC1 tandem repeat units, wherein said nucleic acid sequence is altered from the native tandem repeat pattern by using alternative codons to reduce homology between the repeats, and an immunomodulator.

28. The pharmaceutical composition of claim 5, wherein the immunomodulator is selected from the group consisting of T-cell co-stimulatory factors and cytokines.

29. The pharmaceutical composition of claim 6, wherein the cytokine is an interleukin.

30. The pharmaceutical composition of claim 5, wherein the immunomodulator is both a T-cell co-stimulatory factor and a cytokine.

31. The recombinant pox virus of claim 5, wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.

32. The pharmaceutical composition of claim 5, wherein the immunomodulator is encoded by a nucleic acid sequence on a separate pox virus from said recombinant pox virus comprising the nucleic acid sequence encoding said immunogenic MUC1 fragment.

33. The pharmaceutical composition of claim 5, wherein the immunomodulator and the immunogenic MUC fragment are both encoded by nucleic acid sequences located on a single pox virus.

34. The pharmaceutical composition of claim 5, wherein said MUC1 fragment comprises about 7 to 15 tandem repeat units.

35. A method of generating an immune response in a mammal having a MUC1-expressing tumor comprising:

(a) administering to the mammal the pox virus of claim 1; and

(b) administering a second amount of pox virus wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.

36. The method of claim 13 wherein said boosting is administered by using an effective amount of second recombinant pox virus from a different viral genus from said pox virus of claim 1.

37. The method of claim 13, wherein said mammal is further administered an immunomodulator.

38. The recombinant pox virus of claim 1 which is rV-MUC1.

39. The method of claim 13 wherein the boosting comprises an effective amount of MUC1 administered as a MUC1 peptide or as a nucleic acid sequence that encodes said MUC peptide.

40. A method of inhibiting or killing MUC1 positive tumor cells comprising:

(a) generating MUC1 specific cytotoxic T-lymphocytes (CTLs) by stimulating harvested lymphocytes in vitro by adding an effective amount of a MUC1 specific antigen to the lymphocytes, alone or in combination with one or more cytokines, to generate said CTLs; and

(b) administering the CTLs alone or in combination with a immunomodulator into a mammal in an amount sufficient to inhibit or kill the MUC1 positive tumor cells.

41. A method for generating an immune response in a mammal that contains a MUC1-expressing tumor comprising administering to said mammal at least one pox virus of claim 4.

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REMARKS

By the present Preliminary Amendment, Applicant has added the heading and cross-reference information suggested by the U.S. Patent and Trademark Office at the appropriate places in the specification. No new matter has been added by virtue of this amendment to the specification.

Claims 1 – 22 have been canceled and claims 23 – 41 have been added. Support for the new claims can be found throughout the application as filed, e.g. page 4, lines 10 – 19. No new matter has been added by virtue of the addition of new claims.

In the event that there are any questions relating to this Amendment or to the application in general, it is kindly requested that the Examiner contact the undersigned attorney concerning the same to expedite prosecution of this application.

Entry of the foregoing and prompt and favorable consideration of the subject application on the merits are respectfully requested.

Date: January 25, 2002

Customer No.: 26770

Respectfully submitted,

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VERSION WITH MARKINGS
TO SHOW CHANGES MADE TO THE SPECIFICATION

IN THE SPECIFICATION:

CROSS-REFERENCE TO RELATED APPLICATIONS

The following application is a continuation of U.S. Serial No. 09/366,670 filed on August 3, 1999, which is a continuation of PCT/US98/03693, filed February 24, 1998, now abandoned, which claimed benefit under 35 U.S.C. §119 of U.S. Provisional Application 60/038,254, filed February 24, 1997.

IN THE CLAIMS

23. (NEW) A recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising approximately 5 to *25* MUC1 tandem repeat units, wherein said nucleic acid sequence is altered from the native tandem repeat pattern by using alternative codons to reduce homology between the repeats.

24. (NEW) The recombinant pox virus of claim 1, wherein the immunogenic MUC1 fragment comprises approximately 7 to 15 MUC1 tandem repeat units.

25. (NEW) The recombinant pox virus of claim 2, wherein the immunogenic MUC1 fragment comprises 10 MUC1 tandem repeat units.

26. (NEW) The recombinant pox virus of claim 1, wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.

27. (NEW) A pharmaceutical composition comprising:

(a) a recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising approximately 5 to 25 MUC1 tandem repeat units, wherein said nucleic acid sequence is altered from the native tandem repeat pattern by using alternative codons to reduce homology between the repeats, and an immunomodulator.

28. (NEW) The pharmaceutical composition of claim 5, wherein the immunomodulator is selected from the group consisting of T-cell co-stimulatory factors and cytokines.

29. (NEW) The pharmaceutical composition of claim 6, wherein the cytokine is an interleukin.

30. (NEW) The pharmaceutical composition of claim 5, wherein the immunomodulator is both a T-cell co-stimulatory factor and a cytokine.

31. (NEW) The recombinant pox virus of claim 5, wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.

32. (NEW) The pharmaceutical composition of claim 5, wherein the immunomodulator is encoded by a nucleic acid sequence on a separate pox virus from said recombinant pox virus comprising the nucleic acid sequence encoding said immunogenic MUC1 fragment.

33. (NEW) The pharmaceutical composition of claim 5, wherein the immunomodulator and the immunogenic MUC fragment are both encoded by nucleic acid sequences located on a single pox virus.

34. (NEW) The pharmaceutical composition of claim 5, wherein said MUC1 fragment comprises about 7 to 15 tandem repeat units.

35. (NEW) A method of generating an immune response in a mammal having a MUC1-expressing tumor comprising:

(a) administering to the mammal the pox virus of claim 1; and

(b) administering a second amount of pox virus wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.

36. (NEW) The method of claim 13 wherein said boosting is administered by using an effective amount of second recombinant pox virus from a different viral genus from said pox virus of claim 1.

37. (NEW) The method of claim 13, wherein said mammal is further administered an immunomodulator.

38. (NEW) The recombinant pox virus of claim 1 which is rV-MUC1.

39. (NEW) The method of claim 13 wherein the boosting comprises an effective amount of MUC1 administered as a MUC1 peptide or as a nucleic acid sequence that encodes said MUC peptide.

40. (NEW) A method of inhibiting or killing MUC1 positive tumor cells comprising:

(a) generating MUC1 specific cytotoxic T-lymphocytes (CTLs) by stimulating harvested lymphocytes in vitro by adding an effective amount of a MUC1 specific antigen to the lymphocytes, alone or in combination with one or more cytokines, to generate said CTLs; and

(b) administering the CTLs alone or in combination with a immunomodulator into a mammal in an amount sufficient to inhibit or kill the MUC1 positive tumor cells.

41. (NEW) A method for generating an immune response in a mammal that contains a MUC1-expressing tumor comprising administering to said mammal at least one pox virus of claim 4.